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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,631	11/30/1999	WOLFGANG A. RENNER	1700.0030002	6512

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	18

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/449,631	Renner et al
Examiner	**Art Unit**
Mary Mosher	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *12/6/01 12/10/01*.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *50-58* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *50-58* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *7*
18) ☒ Interview Summary (PTO-413) Paper No(s). *18*
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 50-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 requires "a non-naturally occurring molecular scaffold", and applicants argue that an important feature of the claimed constructs is that the organizer is not a naturally occurring component of the core particle. However, in the specification, "non-natural" is defined more broadly, see e.g. page 14, and there is no explicit definition of "non-naturally occurring" in the specification. The claim does not explicitly state that the organizer is not a naturally occurring component of the core particle. Therefore, it is not clear if the claim requires the "important feature" emphasized in the argument, or if the claim merely requires a scaffold that is in some way different from a product of nature. This affects the dependent claims 51, 54, 57, and 58.

In addition, claim 50 recites a "core" and a "virus-like particle". For some viruses, there is a distinction between a core particle and a virus-like particle. For example, Hepatitis B virus forms particles with core antigen (HBcAg) or with surface antigen (HbsAg), and Bluetongue virus forms distinct core-like particles and virus-like particles with different numbers and types of subunits. It is not clear if the intent is any virus-like particle or more narrowly a core-like particle.

In addition, claims 57 and 58 recite exactly the same material as claims 50 and 51, but in the claim preamble recite an intended use "a vaccine composition" instead of a "composition".

Since the claims are otherwise identical, it is not clear whether or not 57 and 58 are duplicates of claims 50 and 51, since they recite the identical ingredients after the preamble. Furthermore, it is not clear if the intent of the claims is to limit the composition to those which induce an immune response protective against disease (as is the conventional meaning of the term "vaccine"), or if the intent is to more broadly claim an immunogenic composition comprising an amount of the material effective to induce an immune response, in a suitable carrier.

Claims 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition, does not reasonably provide enablement for an immunoprotective vaccine composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification provides teachings on making virus-like particles with attached antigens, but provides no teachings on inducing an immune response sufficient to prevent disease. The art recognized that protection against disease is unpredictable, particularly for cancer and for many of the infectious diseases. While one skilled in the art would readily accept that the particles would induce a useful immune response, one skilled in the art would not unquestioningly accept assertions that such particles would induce a protective response against any and all diseases. Considering the limited teachings in the specification, the state of the art, and the lack of working examples showing protection against disease, it is concluded that undue experimentation would be required to enable the vaccines, as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 50, 51, 54, 57, and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Birkett 6,231,864. Birkett teaches a hepatitis B core protein particle, modified by insertion of a chemically reactive residue, and the reactive residue linked to a hapten. See for example claim 1 of the patent. The core protein particle is the same as the hepatitis B particle in applicant's example 23, and therefore the HBcAg core particle is assumed to be included within the term "virus-like particle". The inserted chemically reactive residue constitutes an unnatural "organizer comprising at least one first attachment site", and being inserted in the core protein sequence indicates it is connected to the core particle by a covalent peptide bond. Therefore the reference teaches a scaffold meeting the claim limitations. The reference teaches a number of peptide haptens , see Table 2, and also teaches covalently attachment of the hapten to the reactive residue by any of a variety of reactions, see for example the working examples 1-3, thereby meeting the limitations for the antigen or antigenic determinant bound to the organizer by a nonpeptide bond. The reference also teaches spatial arrangement of the hapten on the tips of the mace-like spikes, indicating an ordered and repetitive array, see working example 4. The reference also teaches use

of the material in vaccines, see column 23 for example. Therefore the reference clearly teaches each and every limitation of the claims.

Allowable Subject Matter

Claims 52, 53, 55, and 56 remain free of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 25, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600